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JC916 U.S. PTO

08-28-00

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. 460.1815USXV  
Anticipated Classification of this Application  
Class: Subclass:  
Prior Application: 09/075,097 filed May 8, 1998  
Examiner: Art Unit:

08/25/00  
JC862 U.S. PTO  
09/648883

08/25/00  
JC916 U.S. PTO

Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is a request for filing a \_\_\_\_\_ continuation-in-part \_\_\_\_\_ continuation **XX** divisional application under 37 CFR 1.53(b), of pending prior application, Serial No. **09/075,097** filed on **May 8, 1998** of **Karla E. Williams and Paul D. Zwick** for **SOFT, FLEXIBLE COMPOSITION AND METHOD FOR MAKING SAME.**

The filing fee is calculated below:

CLAIMS AS FILED, LESS ANY CLAIMS CANCELLED BY AMENDMENT BELOW				
FOR	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE
TOTAL CLAIMS	22 - 20 =	2	x \$18.00	\$36.00
INDEPENDENT CLAIMS	2 - 3 =	0	x \$78.00	\$0
MULTIPLE DEPENDENT CLAIM FEE				x \$260.00 = \$0
TOTAL FILING FEE				\$726.00
1/2 FILING FEE FOR SMALL ENTITY				\$0

1. **XX** A check in the amount of \$ **726.00** is enclosed.
2. **XX** The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §§1.16 and 1.17 which may be required with this communication or during the entire pendency of the application, or credit any overpayment, to **Deposit Account No. 01-0467**. A duplicate copy of this Form is enclosed.
3. **XX** Cancel in this application original claim(s) **1 - 44** of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
4. **XX** A copy of the preliminary amendment, specification and declaration of **Karla E. Williams** are enclosed.
5. **XX** Amend the specification by inserting before the first line the sentence: --- This is a \_\_\_\_\_ continuation, **XX** division, of application Serial No. **09/075,097**, filed **May 8, 1998**, pending, which is a continuation of application Ser. No. **08/547,766** filed **October 24, 1995**, which issued as U.S. Patent No. 5,986,000, which is a

continuation-in-part of application Ser. No. **08/447,289** filed **May 22, 1995**, which issued as U.S. Patent No. 5,681,894.

6. XX The prior application is assigned of record to:  
**Playtex Products, Inc.**

7. XX The power of attorney in the prior application is to:  
**CHARLES N.J. RUGGIERO**

- a. The power appears in the original papers in the prior application.
- b. Address all future communications to : **CHARLES N.J. RUGGIERO, ESQ.**

**OHLANDT, GREELEY, RUGGIERO & PERLE, L.L.P.**  
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8. XX A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claim in the prior application.)

9. XX Priority of application Serial No. **08/447,289** filed on **May 22, 1995**, Serial No. **08/547,766** filed on **October 24, 1995** and Serial No. **09/075,097** filed on **May 8, 1998** are claimed under 35 U.S.C. §120;

10. XX I hereby verify that the attached papers are a true copy of prior application serial no. **09/075,097** as originally filed on **May 8, 1998**.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Accepted 25, 2000  
August 25, 2000

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CERTIFICATE OF EXPRESS MAILING

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Certificate No. **EL587707270US**, service under 37 CFR §1.10 and is addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231, on August 25, 2000.

Heather A. Fiorella  
(Typed name of person mailing paper)

Heather A. Fiorella  
(Signature of person mailing paper)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Williams, et al.

Serial No.: Not yet assigned

Filed: Herewith

For: Soft, Flexible Composition and Method for  
Making Same

Examiner: Not yet assigned

Art Unit: Not yet assigned

Docket No.: 460.1815USXV

August 25, 2000

**Box PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, DC 20231**

**PRELIMINARY AMENDMENT**

Simultaneous with the filing of the above-identified application and in advance of prosecution, please amend the above-identified application as follows.

**IN THE SPECIFICATION:**

Please amend the specification as follows:

Page 1, lines 4-5, delete "This application is a continuation-in-part of application Serial No. 08/447,289, filed May 22, 1995, pending." and insert therefor --This application is a divisional

of application Ser. No. 09/075,097 filed May 8, 1998, pending,  
which is a continuation of application Ser. No. 08/547,766 filed  
October 24, 1995, which issued as U.S. Patent No. 5,986,000,  
which is a continuation-in-part of application Ser. No.  
08/447,289 filed May 22, 1995, which issued as U.S. Patent No.  
5,681,894.--

Page 18, line 10, delete "59.80" and insert therefor --191.9--;  
same line, delete "70.13" and insert therefor --277.5--;  
line 11, delete "(6.37)" and insert therefor --(20.4)--;  
same line, delete "(7.29)" and insert therefor --(28.9)--;  
line 13, delete "32.47" and insert therefor --104.2--;  
line 14, delete "(3.76)" and insert therefor --(11.8)--;  
line 23, delete "89.54" and insert therefor --239.4--;  
same line, delete "143.20" and insert therefor --474.8--;  
line 24, delete "(9.94)" and insert therefor  
--(26.6)--;  
same line, delete "(23.90)" and insert therefor --(59.3)--;  
line 26, delete "39.13" and insert therefor --113.0--;  
line 27, delete "(6.09)" and insert therefor  
--(17.6)--.

Page 19, line 17, delete "32" and insert therefor --104--;  
line 18, delete "60" and insert therefor --192--;  
line 19, delete "70" and insert therefor --278--;

line 21, after "0.46 lbs.-inch.", insert -- Preferably, with barrels of this dimension, the thermoplastic elastomer will be used in an amount sufficient to adjust the energy needed to compress the tampon applicator barrel by 0.25 inches to less than 0.26 lbs.-inch and adjust the supportable load of the tampon applicator to less than about 2.06 lbs.--.

Page 20, line 11, delete "39" and insert therefor --113--;

line 13, delete "89" and insert therefor --240--;

same line, delete "143" and insert therefor --475--;

line 17, after "lbs.-inch." insert --Preferably, with barrels of this dimension, the modulus of elasticity will be less than 79 psi, and the thermoplastic elastomer will be used in an amount sufficient to adjust the energy needed to compress the tampon applicator barrel by 0.25 inches to less than 0.36 lbs.-inch and adjust the supportable load of the tampon applicator to less than about 2.83 lbs..--.

#### **REMARKS**

This application now contains 22 claims, namely claims 45 through 66. Claims 1 through 44 have been cancelled with the filing of the application.

The specification has been amended to correct the numerical Young's modulus, or "modulus of elasticity," numbers in Table B on page 18 of the application. The protocol used to test the flexibility of each tampon applicator barrel is set forth in the specification at page 17, lines 8 through 15. The quantitative test results were set forth in the application in the original Table B on page 18.

The comparison test of the applicator barrels was conducted on an Instron testing device, model no. 1122. The Instron device has computer software (Software series 9, Version 6.05) that calculates the Young's modulus of elasticity from data compiled during each test run. As per the Declaration of Karla Williams, an inventor of the above-identified application, the software has various options for method of calculation. The calculation method used, 19.3, was an "automatic calculation method" in which some dimensions are entered automatically. This method required that the diameter of the tampon applicator barrels be entered. While this calculation method called for "gauge length", which is a second entry of the applicator barrel's diameter, it was assumed that this "automatic calculation method" would automatically insert the proper "gauge length", namely the applicator barrel diameter. Instead, however, the "gauge length" defaulted to a constant of 0.187 inches. A "manual calculation method", 18.3, should have been used that required that the

barrel diameter be entered both as the "diameter" and "gauge length".

As a result of the calculation method used, a default gauge length of 0.187 inches was used to calculate the Young's modulus of each tampon applicator barrel tested, including the known branded tampon applicator barrels and the tampon applicator barrels of the present invention.

Since the actual diameters of the tested tampon applicator barrels varied between about 0.50 inches to about 0.74 inches, each Young's modulus calculated by the Instron Device was approximately one-third of the actual Young's modulus for that tampon applicator barrel. Since the ratio of Young's modulus for the preferred composition applicator barrels to the Young's modulus for the known branded applicator barrels was as expected, the accuracy of the actual numbers calculated was assumed correct.

The corrected Young's modulus may be obtained by using the following conversion equation:

$$\frac{\text{Corrected Young's Modulus}}{0.187} \times \text{Gauge Length (Diameter of Applicator Barrel)}$$

Thus, Table B, as corrected, should read as follows:

TABLE B: Instron Compression Testing

Tampon applicator barrels having an outside diameter about 0.67 inches +/- .07 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS psi (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic Applicators	2.22 to 3.59 (0.16) (0.22)	191.9 to 277.5 (20.4) (28.9)	0.28 to 0.46 (0.02) (0.03)
Preferred Composition Applicator	1.74 (0.10)	104.2 (11.8)	0.22 (0.01)

Tampon applicator barrels having an outside diameter about 0.56 inches +/- .06 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS psi (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic Applicators	3.11 to 4.85 (0.28) (0.27)	239.4 to 474.8 (26.6) (59.3)	0.40 to 0.62 (0.04) (0.05)
Preferred Composition Applicator	1.96 (0.20)	113.0 (17.6)	0.25 (0.03)

This corrected data supports the present invention as originally filed. The corrected Young's modulus for the applicator barrel of the present invention having a diameter about 0.56 inches is about 113.0, which is at least one-half of the corrected Young's modulus values obtained for the known branded applicator barrels having approximately the same diameter. The corrected Young's modulus for the applicator barrel of the present invention having a diameter of about 0.67 inches is about 104.2, which is also about one-half of the corrected Young's modulus values obtained for the known-branded

applicator barrels having approximately the same diameter. This ratio of corrected Young's modulus for applicator barrels of the present invention to known branded applicator barrels is consistent with the ratio of the corresponding uncorrected Young's modulus for applicator barrels of the present invention and the known branded applicator barrels set forth in original Table B of the application.

It should be understood that the amendments to Table B do not present new matter. Young's modulus is a constant value for any specific material having a certain size. The composition of the preferred composition applicator barrel is set forth in the application at page 15, Table A, and at page 22, as composition D in Table C. Therefore, any person, let alone one of ordinary skill in the art, using the information in the originally filed application and calculating Young's modulus, would obtain the corrected Young's modulus values as now set forth herein. Thus, since the correct Young's modulus for the tampon applicator barrel of the present invention is inherent in the composition that is clearly and definitely disclosed in the application at the pages mentioned above, no new matter is being added by the amendments made to Table B or to the claims.

DECEMBER 2000  
Preliminary Amendment

Page 19, lines 17 through 19, and page 20, lines 11 and 13, of the specification have been amended to reflect the corrected Young's modulus values of amended Table B.

A copy of an executed Declaration of Karla Williams, originally submitted in application Ser. No. 08/547,766, which issued as U.S. Patent No. 5,986,000, and again in copending application Ser. No. 09/075,097, setting forth the facts concerning the unintentional error, discussed above, is attached herewith.

In addition, the specification has been amended to insert matter disclosed in original claims 5, 7, 9, 11, and 13. These amendments to the specification have already been considered and entered in application Ser. No. 08/547,766, which issued as U.S. Patent No. 5,986,000.

In view of the foregoing, applicants respectfully request entry of this preliminary amendment.

Respectfully submitted,



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SOFT, FLEXIBLE COMPOSITION  
AND METHOD FOR MAKING SAME

RELATED APPLICATION

This application is a continuation-in-part of application Serial No. 08/447,289, filed May 22, 1995, pending.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to a soft, flexible material. More particularly, it relates to a thermoplastic composition that can be used to make a variety of products that are soft and flexible. The thermoplastic composition is, preferably, a combination of a polyolefin and thermoplastic elastomeric materials. In addition, the thermoplastic composition may include one or more additional thermoplastic materials. Some uses envisioned for this composition are, for example, catamenial devices, baby care products, such as baby bottles and holders, pacifiers, toothbrushes and containers. One particular use of the composition is for a tampon applicator and especially a tampon applicator barrel, that will be more comfortable and has a greater ease of insertion into the vagina

greater ease of insertion into the vagina than known such applicator barrels.

## II. Description of the Prior Art

Polyethylene is a thermoplastic that is the standard resin used to produce a number of products, including plastic tampon applicators. A softer applicator, especially an applicator barrel, that is more comfortable is a desirable feature of a tampon applicator in order to provide improved ease of insertion.

It is generally known that thermoplastic elastomer articles may be combined with polyethylene to improve the strength and toughness of such articles. For example, U.S. Patent No.

4,593,063 to M.A. Jones, et al., which issued June 3, 1986, provides a reinforced rigid polymer blend which yields a high gloss finish when injection molded. The thermoplastic elastomer includes 25 to 35 percent of a butadiene thermoplastic elastomer having a molecular weight of about 70,000 to about 100,000, a styrene content from about 25 to about 44 percent by weight and a melt flow rate from about 8 to about 15 grams per 10 minutes. The butadiene thermoplastic elastomer is blended with from about 54 to about 75 percent of a rigid polymer, such as polyethylene.

Polymers have also been combined with polyethylene to improve their reaction to each other when heated or otherwise processed.

For example, U.S. Patent No. 4,678,834 to D.W. Boivin, et al., which issued July 7, 1987, provides a polyolefin blend comprising a major portion of polyethylene and a minor portion of a second polymer, such as a styrene-butadiene-styrene copolymer. The second polymer contains a reactive agent that is capable of reacting with polyolefins in a molten state. The reactive agent modifies or stabilizes the polymer during processing or during use.

0 Polymers may also be added to polyethylene to permit a breakdown of its structural composition. Polyethylene, which is normally stable, has also been combined with less stable materials to produce biodegradable products. Such biodegradable products include ingredients that cause oxidative actions in order to break down the polyethylene. For example, U.S. Patent 15 No. 5,212,219 to G.J.L. Griffin, which issued May 18, 1993, provides a degradable article prepared from a blend of polyethylene and a less stable polymer or copolymer, such as a styrene-butadiene block copolymer. The composition further comprises an antioxidant active over a limited period and a pro-oxidant that causes a sharp loss of physical strength on depletion of the anti-oxidant. In addition, the presence of 20 filler particles of a biologically sensitive material accelerates the biological breakdown of the polymer/copolymer blend.

Improvements to the pelletizability and drapability of a polymer composition, without causing the composition to biodegrade, are also known. For example, U.S. Patent No. 4,833,195 to A.M. Adur, et al., which issued May 23, 1989, provides a thermoplastic polymer composition that can be conveniently converted into a drapable film or fabric. The composition has a low Shore A hardness, i.e., below about 95, and a high melt flow rate about 30 grams/10 minutes to 1100 grams/10 minutes at 230 degrees Celsius and 2.16 kilograms. Drapability 10 is an important property of products that drape against a user's skin, such as baby diapers or sanitary napkins.

However, none of the above patents describe or suggest a tampon applicator that is composed of such materials. In fact, 15 none of the above patents suggest the inventive combination of polyethylene and the unique elastomeric composition which improves flexibility, strength and tear resistance and, perhaps, softness, and can function as a compatibilizer with other thermoplastic polymeric materials. Thus, the above patents do not suggest a flexible, soft tampon applicator having a unique 20 blend of polyethylene and a rubber type composition that includes a thermoplastic elastomer (TPE), namely a styrene-butadiene-styrene block copolymer, which applicator provides for comfortable and easy insertion into the vagina.

Further, thermoplastic resins are much less expensive than 25 elastomeric materials. To minimize the costs of tampon

applicators, one desires the greatest amount of thermoplastic resin as possible in the composition, but without adverse affects. Accordingly, to achieve the benefits of a flexible and easy to insert tampon applicator barrel and yet minimize costs, it is desired to use as little as possible of the elastomer components and as much as possible of the thermoplastic resin component in the tampon applicator barrel.

Other projected products, such as, for example, a holder for nurser liners or a nurser bottle, may desire the flexibility of the material in order to assist a child or parent in gripping the product and, perhaps, squeeze the product to remove contents.

## SUMMARY OF THE INVENTION

Against the foregoing background, it is a primary object of the present invention to provide a composition that comprises a polyolefin and a thermoplastic elastomer.

It is another object of the present invention to provide such a composition that favorably adjusts the modulus of elasticity of the composition.

It is yet another object of the present invention to provide such a composition in a thermoplastic-type tampon applicator so that the barrel, in particular, is soft and flexible to provide more comfort and improved ease of insertion.

It is a further object of the present invention to provide such a tampon applicator at least one styrene-butadiene-styrene block copolymer to achieve such desired properties.

To accomplish the foregoing objects and advantages, the present invention, in brief summary, is a soft, flexible composition that comprises a thermoplastic resin and at least two styrene-butadiene-styrene block copolymers, each having a different percent by weight of styrene in an amount sufficient to reduce the modulus of elasticity.

A preferred use of the composition is as a tampon applicator barrel that is more comfortable and has improved ease of insertion into the vagina. The tampon applicator barrel comprises a thermoplastic resin and at least one thermoplastic elastomer in an amount sufficient to adjust favorably the modulus of elasticity of the tampon applicator barrel.

More specifically, the present invention is a soft, flexible tampon applicator that provides more comfort and improved ease of insertion into the vagina by the combination of a low density polyethylene and at least one styrene-butadiene-styrene block copolymer. In one preferred embodiment, there are at least two styrene-butadiene-styrene block copolymers, each having a different percent by weight of styrene.

In a most preferred embodiment, there are three styrene-butadiene-styrene block copolymers each having a percentage by weight of styrene that is different than that of the other two copolymers. In particular, the first styrene-butadiene-styrene block copolymer has about 29 percent by weight of styrene, the second styrene-butadiene-styrene block copolymer has about 31 percent by weight of styrene, and the third styrene-butadiene-styrene block copolymer has about 43 percent by weight of styrene.

The polymeric resin should further comprise one or more of the following: a plasticizer and a compatibilizer/flow modifier, and may further comprise other ingredients, such as a pigment, a slip/mold release agent, an antioxidant and, perhaps, an antistat 5 ingredient.

The present invention is also a method for making a composition that can be made into a soft, flexible product. An elastomer composition is melted and combined to form a melted resin which is then extruded into a plurality of soft resin 10 pellets. The plurality of soft resin pellets are then dry blended with a plurality of pellets of a polyolefin, for example, low density polyethylene to form a pellet mixture. Finally, the pellet mixture is melted together to form a polymeric compound 15 that may be molded to a desired shape. In a preferred embodiment, the method is used to make a tampon applicator, especially an applicator barrel, that has a soft and flexible structure for more comfort and improved ease of insertion into the vagina.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a new polymeric compound or composition that is a combination of a polyolefin and a rubber type composition that adjusts the softness and flexibility of the 5 polymeric compound. As stated above, while it is envisioned that this material may be used to form a variety of products, such as, for example, baby or nurser bottles and holders, pacifiers, toothbrushes and containers, a preferred application is for catamenial devices. A particularly preferred applicator is a 10 tampon applicator, especially an applicator barrel, composed of this new polymeric compound.

To minimize costs, it is preferable that the tampon applicator have an applicator barrel that uses the polymeric compound of the present invention, while the plunger is made, perhaps, of less expensive material. A softer applicator barrel 15 is more comfortable and is a desirable feature of a tampon applicator in order to provide improved ease of insertion. Accordingly, the present application is directed to a tampon applicator barrel, however it can be used for the entire tampon 20 applicator.

The polymeric compound comprises polyolefin and a rubber type composition that adjusts the softness and flexibility of the polymeric compound and, thus, the tampon applicator. For the

preferred embodiment, the polyolefin is a low density polyethylene and the rubber type composition includes a thermoplastic elastomer. The thermoplastic elastomers could include thermoplastic vulcanizates, thermoplastic olefins, styrene block copolymers, thermoplastic urethanes and combinations thereof. In the most preferred embodiment, the thermoplastic elastomer is a plurality of styrene-butadiene-styrene block copolymers.

The primary supporting structure of the soft applicator barrel is provided by the polyolefin. The preferred type of polyolefin is polyethylene, and, more preferably, low density polyethylene. The polyethylene can be a linear low density polyethylene. For the preferred embodiment, the polyolefin is about 25 to about 75 percent by weight of the total weight of the polymeric compound.

The thermoplastic elastomers are combined with the polyolefin in amounts sufficient to adjust the elasticity of the polymeric compound.

Styrene-butadiene-styrene block copolymers are the preferred thermoplastic elastomers. A combination of three different types of styrene-butadiene-styrene block copolymers having different contents of styrene is the more preferred. In a most preferred embodiment, a first styrene-butadiene-styrene block copolymer has 29 percent by weight of styrene in the block copolymer, a

molecular weight of 80,000 and a melt flow rate 8 gram per 10 minutes, a second styrene-butadiene-styrene block copolymer has 31 percent by weight of styrene, a molecular weight of 100,000 and a melt flow rate less than 1 gram per 10 minutes, and a third styrene-butadiene-styrene block copolymer has 43 percent by weight of styrene, a molecular weight of 58,000 and a melt flow rate 23 gram per 10 minutes. The melt flow rate for all three styrene-butadiene-styrene block copolymers is measured at 200 degrees Celsius with a 5.0 kg load. Such first, second and third styrene-butadiene-styrene block copolymers are commercially available as Vector Resin 8550, Vector Resin 2518, and Vector Resin 6241, respectively. These copolymers are manufactured by Dexco Polymers (a Dow/Exxon Partnership) of Houston, Texas.

Each of the first, second and third styrene-butadiene-styrene block copolymers is about 5.5 to about 16.6 percent by weight of the total weight of the polymeric compound. Accordingly, the weight of the block copolymers is about 16.5 to about 49.80 by weight of the total weight of the polymeric compound.

The combination of these three block copolymers has been found to provide the optimum viscosity desired so that the thermoplastic resin phase, namely polyethylene, and the rubber phase are compatible.

The rubber type composition that is added to the polyolefin may also include other materials. It is preferred that a plasticizer, such as mineral oil, be used to reduce the viscosity and hardness. The plasticizer is about 5 to about 15 percent by weight of the total weight of the polymeric compound. In addition, the rubber type composition may contain a filler, such as CaCO<sub>3</sub> or talc.

It is also preferred that the polymeric compound include a compatibilizer/flow modifier, which assists in the blending or compatibilization of the thermoplastic resin and the rubber materials, and to improve the tear resistance and elongation properties of the compound. Preferably, the compatibilizer/flow modifier is a copolymer. In the preferred embodiments, the copolymer is an alpha olefin copolymer, namely an ethylene copolymer. In the most preferred embodiment, the ethylene copolymer is ethylene methyl acrylate. Alternative alpha olefin copolymers that can be used are ethylene vinyl acetate, ethylene ethyl acrylate, ethylene butyl acrylate and mixtures thereof. Ethylene methyl acrylate is the most preferred since it, unlike ethylene vinyl acetate, will not decompose under high molding temperatures, and is less expensive than either ethylene ethyl acrylate or ethylene butyl acrylate.

The compatibilizer/flow modifier is present in an amount about 2.9 to about 8.6 percent by weight of the total weight of

the polymeric compound.

The rubber type composition may further include additives, such as a pigment or color additive, a slip/mold release agent, an antioxidant and/or an antistat, that may be necessary to facilitate the manufacture or otherwise improve the quality of the tampon applicator or barrel.

The pigment, that is chosen to provide the desired aesthetic effect, is preferably titanium dioxide. It is about 0.5 to about 5 percent weight of the total weight of the polymeric resin.

The slip/mold release agent is, preferably, a fatty acid amide, such as, erucamide. Alternatively, the slip/mold release agent can be metallic stearates, calcium stearate, ethylene bis stearamide and ethylene bis oleamide. In a preferred embodiment for use in a tampon applicator barrel, erucamide is present in an amount about 0.8 percent by weight of the total weight of the polymeric compound. While erucamide is a preferred slip release agent, an erucamide slip agent may undergo substantial blooming subsequent to molding. Such blooming will result in an agglomeration of the erucamide slip release agent on the surface of the molded polymeric article that can cause gumming and contamination problems in equipment if substantial post-molding handling of the article is required. Surprisingly, stearyl erucamide has been found to avoid the blooming problem. The use of higher amounts, about 3%, of stearyl erucamide is preferred.

Accordingly, stearyl erucamide has been found to particularly improve the process of manufacture of a tampon applicator and tampon applicator barrel that require significant handling after molding. When stearyl erucamide is used, a higher amount of the release agent, for example up to about 3 percent by weight of the total weight of the composition, may be used. Accordingly, the slip/mold release agent can be present in a range about 0.4 to about 3 percent by weight of the total weight of the polymeric compound.

The antioxidant provides stability to the polymeric compound. It is preferred that the antioxidant be a combination of two antioxidants. One antioxidant is tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)] methane. The other antioxidant is tris (2, 4-di-tert-butyl phenyl) phosphite. Such antioxidants/stabilizers are manufactured under the product names Irganox 1010 and Irgafos 168, respectively, by Ciba-Geigy Corporation. Each antioxidant is about 0.05 to about 0.15 percent by weight of the total weight of the polymeric compound.

When there is substantial handling of the molded article, such as, for example, a tampon applicator or tampon applicator barrel, the most preferred embodiment of the present composition has the following ingredients and their approximate percent by weight of the total composition:

TABLE A

about 63%	low density polyethylene;
about 8%	first styrene-butadiene-styrene block copolymer having about 29 percent of styrene;
about 8%	second styrene-butadiene-styrene block copolymer having about 31 percent of styrene;
about 8%	third styrene-butadiene-styrene block copolymer having about 43 percent of styrene;
about 7%	mineral oil as the plasticizer;
about 4%	ethylene methyl acrylate as the compatabilizer/flow modifier;
about 1%	titanium dioxide as the pigment;
about 1.5%	stearyl erucamide as the slip/mold release agent;
less than 1%	tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]
	methane as a stabilizer/antioxidant; and
less than 1%	tris (2, 4-di-tert-butyl phenyl) phosphite as a stabilizer/antioxidant.

Higher styrene contents would tend to make the elastomer material less soft and less flexible. In a preferred embodiment of the polymeric compound, the amount of the third styrene-butadiene-styrene block copolymer is about one-half of one percent less than the amount of the first or second styrene-butadiene-styrene block copolymers.

It is to be understood that an antistatic agent or antistat may be added to the polymeric compound but is not a part of the preferred embodiment. The antistat imparts a slight to moderate degree of electrical conductivity to plastic compounds, thus preventing the accumulation of electrostatic charges on the soft applicator. The antistat may be incorporated in the ingredients before molding, or applied to the outer surface of the tampon applicator or barrel after molding.

The preferred method for making the preferred polymeric compound that is formed into an applicator or applicator barrel is as follows. The three styrene-butadiene-styrene block copolymers, mineral oil, ethylene methyl acrylate, stearyl erucamide and the antioxidants (and pigment, if used) are weighed and then combined in a twin screw extruder that melts and blends the ingredients and forms a melted resin. The melted resin is then extruded and cut into soft resin pellets. These soft resin pellets are then dry blended with pellets of the remaining ingredient, i.e. the low density polyethylene, to form a pellet mixture. The pellet mixture of low density polyethylene pellets and soft resin pellets are then melted and injection molded to form the desired shape for the soft tampon applicator or applicator barrel.

An alternative method for making the preferred polymeric compound that is formed into an applicator or applicator barrel includes weighing all ingredients including the low density polyethylene and then combining them in a twin screw extruder to form the melted compound. The melted compound is then extruded and cut into pellets which are then injection molded to form the desired shape for the tampon applicator or applicator barrel.

In order to exemplify the effectiveness of the composition comprising low density polyethylene and the styrene-butadiene-styrene block copolymers verses conventional

low density polyethylene based compositions, the following comparison test was conducted of tampon applicator barrels.

An element of "softness" is flexibility. In order to test for flexibility, Instron compression testing was performed to compare differences in flexibility of the tampon applicator barrel of the preferred embodiment against the four known thermoplastic applicator barrels.

The Instron compression test was designed to treat the whole barrel as a tubular specimen. A 5/8 inch wide platen is used to radially compress the applicator barrel against a 6 inch anvil. The specimen is placed on the anvil so that the platen engages the barrel at an axial location between 1 3/8 inch and 2 3/16 inch as measured from the finger grip end of the applicator barrel. The specimen is compressed by a total of 0.25 inch at a rate of 0.5 inch/minute.

As shown in Table B below, the Instron compression test produced the following results.

TABLE B: Instron Compression Testing

Tampon applicator barrels having an outside diameter about 0.67 inches +/- .07 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS PSI (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic applicators			
0	2.22 to 3.59 (0.16)	59.80 to 70.13 (6.37)	0.28 to 0.46 (0.02)
Preferred Composition Applicator	1.74 (0.10)	32.47 (3.76)	0.22 (0.01)

Tampon applicator barrels having an outside diameter about 0.56 inches +/- .06 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS PSI (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic applicators			
20	3.11 to 4.85 (0.28)	89.54 to 143.20 (9.94)	0.40 to 0.62 (0.04)
Preferred Composition Applicator	1.96 (0.20)	39.13 (6.09)	0.25 (0.03)

The standard deviation of the four known branded thermoplastic applicator barrels is different for each applicator barrel. Accordingly, there is a range for the known thermoplastic applicators with a standard deviation for the lowest number and largest number in the range. It should be understood that the grade of material, diameter and wall thickness of the barrel are the three factors that affect flexibility, and that flexibility is determined by the load, Young's modulus or modulus of elasticity, and energy.

Young's modulus, also known in the art as modulus of elasticity, is a measurement for flexibility. It is the ratio of a nominal stress to corresponding strain below the proportional limit of a material. Young's modulus is expressed in force per unit area, usually lbs. per square inch (PSI) as shown in Table B.

The larger diameter, preferred composition applicator has an outside diameter about 0.60 inches. As shown in Table B, it has been found significantly more flexible than known thermoplastic applicators. For the larger outside diameter applicator barrels, about 0.60 to about 0.74 inches (0.67 inches +/- .07 inches), the load results indicate that the applicator barrel made with the preferred polymeric compound requires about 1.74 lbs. to radially compress the applicator barrel by 0.25 inches, whereas the four known thermoplastic applicator barrels require about 2.22 lbs. to about 3.59 lbs. In addition, Young's modulus or the modulus of elasticity for the present applicator barrel is about 32 psi, whereas the known thermoplastic applicators is about 60 psi to about 70 psi. Also, the energy to compress by 0.25 inches the present applicator barrel is about 0.22 lbs.-inch, whereas the known applicator barrels are about 0.28 to 0.46 lbs.-inch.

It would be expected that the smaller the outside diameter of the barrel, the higher the Young's modulus. Accordingly, the results of the present applicator barrel (having an outside diameter of about 0.60 inches) to the known applicator barrels

having an outside diameter from 0.60 to 0.74 is even more remarkable.

For the smaller outside diameter applicator barrels, i.e. about 0.50 to about 0.62 inches (0.56 inches +/- .06), the load results indicate that the applicator barrel made with the preferred polymeric compound (having an outside diameter about 0.54 inches) requires about 1.96 lbs. to radially compress the applicator barrel 0.25 inches, whereas the known thermoplastic applicator barrels require about 3.11 lbs. to about 4.85 lbs. to 0 compress 0.25 inches. In addition, the modulus of elasticity for the present applicator barrel is about 39 psi, whereas the modulus of elasticity for the known thermoplastic applicator barrels is about 89 psi to about 143 psi. Also, the energy to compress by 0.25 inches the present applicator barrel is about 5 0.25 lbs.-inch, whereas such energy to compress the known applicator barrels the same amount is about 0.40 to 0.62 lbs.-inch.

Thus, present or soft applicators made with the preferred polymeric compound of the present invention have a load, modulus of elasticity and energy approximately one-half that of all known thermoplastic applicator barrels. In addition, applicator barrels of the present invention have been found by consumers as a unique, softer applicator barrel due to the tactile feel of the applicator barrels.

In addition to improved "softness" and "flexibility", the polymeric compound or composition of the present composition has been found to have improved strength and tear resistance. The following test demonstrates the unexpected improvement in strength and tear resistance.

Samples A through D were manufactured by combining three block copolymers, a plasticizer, a compatibilizer/flow modifier, mold release agents, antioxidants/stabilizers and a pigment, and in the percentages set forth in Table C. They were compared with

0      a "comparative" sample made of a combination of one block  
1      copolymer, along with an analogous plasticizer, mold release  
2      agents, antioxidants/stabilizers and pigment. For each sample  
3      and the comparative, the mixed compositions were made according  
4      to the preferred method set forth above. In particular, each  
5      mixed composition was passed through a twin screw extruder that  
6      melted and blended the ingredients and extruded to form a melted  
7      resin that is then cut into soft resin pellets. The soft resin  
8      pellets were then dry blended with pellets of low density  
9      polyethylene to form a pellet mixture. The pellet mixture was  
20     then melted and injection molded to form ASTM test articles. The  
21     four samples and the comparator were evaluated for elongation,  
22     tensile strength, and tear resistance (see Table D). As  
23     evidenced by the results of Table D, the four samples, each with  
24     three block copolymers, as compared to the one block copolymer  
25     comparative, demonstrated significantly improved strength and  
      tear resistance properties.

In addition, the preferred composition noted as D in Table D and also set forth in Table A, has the best combination of softness, flexibility, strength and tear resistance of all compositions tested.

TABLE C

<u>Ingredients</u>	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>Comparative</u>
Styrene-butadiene-styrene (29% styrene)	10.48	8.90	11.93	8.0	29.97
Styrene-butadiene-styrene (31% styrene)	10.48	8.90	11.93	8.0	-
Styrene-butadiene-styrene (43% styrene)	7.20	8.32	8.22	8.0	-
Mineral Oil	7.13	8.12	8.12	7.0	10.23
Ethylene-methyl acrylate (20MI)	-	4.68	-	4.0	-
Stearyl erucamide	-	1.83	-	1.5	0.63
Irganox 1010	<0.1	<0.1	<0.1	<0.1	<0.1
Irgafos 168	-	<0.1	<0.1	<0.1	<0.1
Low density polyethylene	58.40	58.40	58.20	63.0	58.20
Ethylene vinyl acetate	4.80	-	-	-	-
Titanium	0.80	0.78	0.80	1.0	0.80
Erucamide	0.64	-	0.63	-	0.63

TABLE D

<u>Sample</u>	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	<u>Comparative</u>
Elongation, % (ASTM D638)	170	246	162	227	86
Tensile Strength psi. (ASTM D638)	820	878	862	917	753
Tear Resistance (ASTM D624)	218	234	167	248	132

The present invention having been thus described with particular reference to the preferred forms thereof, it will be obvious that various changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the appended claims.

Wherefore, we claim:

1. A tampon applicator barrel comprising:

a thermoplastic resin; and

a thermoplastic elastomer in an amount sufficient to adjust elasticity so that the modulus of elasticity of the tampon applicator barrel is less than about 53 psi.

2. The tampon applicator barrel of claim 1, wherein the modulus of elasticity is less than about 46 psi.

3. The tampon applicator barrel of claim 1, wherein the tampon applicator barrel has an outside diameter about 0.67 inches, a wall thickness about 0.027 inches, and the modulus of elasticity is about 32 psi.

4. The tampon applicator barrel of claim 1, wherein the tampon applicator barrel has an outside diameter about 0.60 and a wall thickness about 0.027 inches, and the modulus of elasticity is less than about 32 psi.

5. The tampon applicator barrel of claim 3, wherein said thermoplastic elastomer is sufficient to adjust the energy needed to compress the tampon applicator barrel by 0.025 inches to less than 0.26 lbs.-inch.

6. The tampon applicator barrel of claim 4, wherein said thermoplastic elastomer is sufficient to adjust the energy needed to compress the tampon applicator barrel by 0.025 inches to about 0.22 lbs.-inch.

7. The tampon applicator barrel of claim 3, wherein said thermoplastic elastomer is sufficient to adjust the supportable load of the tampon applicator to less than 2.06 lbs.

8. The tampon applicator barrel of claim 4, wherein the supportable load of the tampon applicator is about 1.74 lbs.

9. A tampon applicator barrel having an outside diameter about .056 inches and a wall thickness about 0.027 inches, comprising:

a thermoplastic resin; and

a thermoplastic elastomer in an amount sufficient to adjust elasticity so that the modulus of elasticity of the tampon applicator barrel is less than 79 psi.

10. The tampon applicator barrel of claim 9, wherein the modulus of elasticity is about 39 psi.

11. The tampon applicator barrel of claim 9, wherein said thermoplastic elastomeric is sufficient to adjust the energy needed to compress the tampon applicator barrel by 0.025 inches to less than 0.36 lbs.-inch.

12. The tampon applicator barrel of claim 11, wherein the energy needed to compress the tampon applicator barrel by 0.025 inches is about 0.25 lbs.-inch.

13. The tampon applicator barrel of claim 9, wherein said thermoplastic elastomeric is sufficient to adjust the supportable load of the tampon applicator barrel to less than 2.83 lbs.

14. The tampon applicator barrel of claim 13, wherein said thermoplastic elastomeric is sufficient to adjust the supportable load of the tampon applicator barrel to about 1.96 lbs.

15. The tampon applicator barrel of claim 1, wherein the thermoplastic resin is a polyolefin.

16. The tampon applicator barrel of claim 15, wherein the polyolefin is a low density polyethylene.

17. The tampon applicator barrel of claim 1, wherein said thermoplastic elastomer is a block copolymer, and wherein said block copolymer is a styrene-butadiene-styrene block copolymer.

18. The tampon applicator barrel of claim 17, wherein said block copolymer is a plurality of styrene-butadiene-styrene block copolymers.

5 19. The tampon applicator barrel of claim 18, wherein said plurality of styrene-butadiene-styrene block copolymers includes three styrene-butadiene-styrene block copolymers, each having a different percent composition by weight of styrene.

10 20. The tampon applicator barrel of claim 1, further comprising a flow modifier.

15 21. The tampon applicator barrel of claim 20, wherein said flow modifier is an ethylene copolymer.

20 22. The tampon applicator barrel of claim 21, wherein said ethylene copolymer is ethylene methyl acrylate.

25 23. The tampon applicator barrel of claim 1, further comprising a plasticizer.

24. The tampon applicator barrel of claim 23, wherein said plasticizer is mineral oil.

25. The tampon applicator barrel of claim 1, further comprising a slip/mold release agent.

26. The tampon applicator barrel of claim 25, wherein said slip/mold release agent is stearyl erucamide.

27. The tampon applicator barrel of claim 1, further comprising an antioxidant.

5 28. The tampon applicator barrel of claim 27, wherein said antioxidant is at least two antioxidants.

29. The tampon applicator barrel of claim 28, wherein said

at least two antioxidants are tetrakis [methylene  
73,5-di-tert-butyl-4-hydroxyhydrocinnamate)] methane and tris  
10 (2,4-di-tert-butyl phenol) phosphite.

30. The tampon applicator barrel of claim 19, further comprising:

an ethylene copolymer; and

a mineral oil.

15 31. The tampon applicator barrel of claim 30, further comprising stearyl erucamide.

32. The tampon applicator barrel of claim 31, further comprising an antioxidant.

33. A tampon applicator barrel having a soft, flexible body for comfort and ease of insertion into the vagina comprising:

a low density polyethylene;

at least three styrene-butadiene-styrene block copolymers,

5 each styrene-butadiene-styrene block copolymer having percentage by weight of styrene different than that of the other two block copolymers;

a compatibilizer/flow modifier; and

a plasticizer.

10 34. The tampon applicator barrel of claim 33, further comprising an antioxidant.

35. The tampon applicator barrel of claim 33, further comprising a slip/mold release agent.

15 36. The tampon applicator barrel of claim 33, wherein a first of said at least three block copolymers has about 29 percent by weight of styrene.

37. The tampon applicator barrel of claim 36, wherein a second of said at least three block copolymers has about 31 percent by weight of styrene.

38. The tampon applicator barrel of claim 37, wherein a third of said at least three block copolymers has about 43 percent by weight of styrene.

39. The tampon applicator barrel of claim 33, wherein said low density polyethylene is about 25 to about 75 percent by weight of the total weight of the tampon applicator barrel.  
5

40. The tampon applicator barrel of claim 33, wherein said each styrene-butadiene-styrene block copolymers is present in an amount about 5.5 to about 16.6 percent by weight of the total  
10 weight of the tampon applicator barrel.

41. The tampon applicator barrel of claim 33, wherein said compatibilizer/flow modifier is an ethylene copolymer, and  
wherein said plasticizer is mineral oil.  
15

42. The tampon applicator barrel of claim 34, wherein said antioxidant is at least two antioxidants, and wherein said at least two antioxidants are tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)] methane and tris (2,4-di-tert-butyl phenol) phosphite.  
15

43. A tampon applicator barrel having a soft, flexible body  
20 for comfort and ease of insertion into the vagina comprising:

a low density polyethylene;

at least three styrene-butadiene-styrene block copolymers,  
each styrene-butadiene-styrene block copolymer having percentage  
by weight of styrene different than that of the other two block  
5 copolymers;

an alpha olefin compatibilizer/flow modifier;

a plasticizer;

a plurality of antioxidants; and

a slip/mold release agent.

10 44. The tampon applicator of claim 43, further comprising a  
pigment.

45. A method for making a tampon applicator barrel having a  
soft, flexible supporting structure comprising the steps of:

combining an elastomeric composition, including melting said  
15 elastomeric composition, to form a melted resin;

extruding said melted resin into a plurality of soft  
pellets;

dry blending said plurality of soft pellets with a plurality of pellets of a low density polyethylene to form a pellet mixture;

melting said pellet mixture together to form a polymeric  
5 compound; and

molding said polymeric compound to a desired shape for the tampon applicator barrel.

46. The method of claim 45, wherein said elastomeric composition includes a plurality of styrene-butadiene-styrene block copolymers, and wherein the step of combining said plurality of block copolymers includes combining said plurality of block copolymers with a plasticizer, a compatibilizer/flow modifier, a slip/mold release agent, and an antioxidant.

47. The method of claim 46, said combining step includes the step of situating said plurality of styrene-butadiene-styrene block copolymers, said plasticizer, said compatibilizer/flow modifier, said slip/mold release agent, and said antioxidant in a twin screw extruder before combining said block copolymers so that said plurality of block copolymers are combined and melted  
20 within said twin screw extruder.

48. The method of claim 46, further comprising the step of combining polyethylene with the elastomeric composition prior to the step of extruding.

49. A soft, flexible polymeric composition comprising:

5           a polyolefin; and

at least two styrene-butadiene-styrene block copolymers, each having a percentage by weight of styrene different than the other, in amounts sufficient to adjust the elasticity of the composition.

10          50. The composition of claim 49, wherein said at least two styrene-butadiene-styrene block copolymers is three styrene-butadiene-styrene block copolymers, each having a different percentage by weight of styrene.

15          51. The composition of claim 50, wherein a first of said at least three block copolymers has about 29 percent by weight of styrene.

52. The composition of claim 50, wherein a second of said at least three block copolymers has about 31 percent by weight of styrene.

53. The composition of claim 50, wherein a third of said at least three block copolymers has about 43 percent by weight of styrene.

54. The composition of claim 50, wherein each of said at least three block copolymers is present in an amount about 5.5 to about 16.6 percent by weight of the total weight of the composition.

55. The composition of claim 49, wherein said polyolefin is low density polyethylene.

10 56. The composition of claim 55, wherein said low density polyethylene is about 25 to about 75 percent by weight of the total weight of the composition.

57. The composition of claim 49, further comprising a flow modifier.

15 58. The composition of claim 57, wherein said flow modifier is an ethylene copolymer.

59. The composition of claim 58, wherein said ethylene copolymer is ethylene methyl acrylate.

60. The composition of claim 49, further comprising a plasticizer.

61. The composition of claim 60, wherein said plasticizer is mineral oil.

62. The composition of claim 60, wherein said plasticizer is about 5 to about 15 percent by weight of the total weight of the composition.

63. The composition of claim 49, further comprising a slip/mold release agent.

64. The composition of claim 63, wherein said slip/mold release agent is stearyl erucamide.

65. The composition of claim 49, further comprising an antioxidant.

66. The composition of claim 65, wherein said antioxidant is selected from the group consisting of tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)] methane and tris (2,4-di-tert-butyl phenol) phosphite.

## ABSTRACT OF THE DISCLOSURE

There is provided a composition comprising a unique

polymeric compound that provides a soft, flexible product. There

is also provided a unique polymeric tampon applicator that is

soft and flexible. When used as a tampon applicator barrel, the

barrel is more comfortable and has improved ease of insertion.

The polymeric compound primarily comprises a thermoplastic resin

and a block copolymer that exhibit unique load, energy and

modulus of elasticity properties. The polymeric compound should

also include a plasticizer and a compatibilizer/flow modifier,

and may include a slip/mold release agent, an antioxidant, and

even a pigment. There is also provided a method for making the

polymeric compound that will be formed into a product, such as an

applicator or applicator barrel in which all of the above

ingredients, except for the thermoplastic resin, are combined and

formed into soft pellets. The soft resin pellets are then dry

blended with pellets of the thermoplastic resin. The mixture of

the thermoplastic resin pellets and the soft resin pellets are

then melted and injection molded into the desired shape. There

is thus provided a method of making a soft, polymeric tampon

applicator or tampon applicator barrel.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Williams et al.

Serial No.: 08/547,766

Filed: October 24, 1995

FOR: SOFT, FLEXIBLE COMPOSITION AND METHOD  
FOR MAKING SAME

Examiner: Mark Warzel

Group: 1511

Attorney Docket No.: 460.1815USU

**COPY**BOX AF  
ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, DC 20231

## DECLARATION

Dear Sir:

1. I, Karla E. Williams, hereby declare and state as follows:

2. I am a citizen of the United States, and reside at 102  
Munsey Road, Emerson, New Jersey, 07630.3. I have been employed at Playtex Products, Inc. continuously  
since September 1982 in the field of Feminine Care Research and  
Development. My current position is Senior Group Leader.4. I am the co-inventor of the subject matter of the above-  
identified patent application. I am familiar with the manner in

which the comparative tests of the present application were conducted.

5. The comparative tests compared known branded thermoplastic applicator barrels to applicator barrels of the preferred composition of the present invention. The test results are set forth in the application at Table B on page 18. The test of the above-mentioned applicator barrels was conducted on an Instron testing device, model no. 1122. The Instron device has computer software (Software series 9, Version 6.05) that calculates the Young's modulus of elasticity from data compiled during each test run. The software has various options for method of calculation. Unfortunately, the calculation method used, 19.3, was an "automatic calculation method" in which some dimensions are entered automatically. This method required that the diameter of the tampon applicator barrels be entered. While the calculation method called for "gauge length", which is a second entry of the barrel's diameter, it was assumed that this "automatic calculation method" automatically inserted the proper "gauge length", namely the barrel diameter. Instead, however, the "gauge length" defaulted to a constant of 0.187 inches. A "manual calculation method", 18.3, should have been used. This method required that the barrel diameter be entered both as the "diameter" and as the "gauge length."

6. The default gauge length was used to calculate the Young's modulus of each tampon applicator barrels tested, including the known branded tampon applicator barrels and the tampon applicator barrels of the present invention. Since the actual diameters of the tested tampon applicator barrels varied between about 0.50 inches to about 0.74 inches, each Young's modulus calculated by the Instron Device was approximately one-third of the actual Young's modulus for that tampon applicator barrel.

7. Thus, the ratio of Young's modulus for the preferred composition applicator barrels to the Young's modulus for the known branded applicator barrels was as expected. Accordingly, the accuracy of the actual numbers calculated was assumed correct. In late 1997, the Young's modulus results were evaluated to confirm test results for another project. At that time, it was discovered there existed a discrepancy between the Young's modulus numbers set forth in the present application and those derived for the second project. However, the source of the discrepancy was unknown.

8. Various possible sources for the discrepancy were evaluated. Accordingly, the manufacturer of the Instron testing device was contacted. The manufacturer was not able to locate the source of the inaccuracies until about November 1997. In December 1997, it became evident that the Young's modulus data submitted in the application was affected, but it was not known what was the

correct data. In January 1998, the corrected Young's modulus data was generated.

9. The corrected Young's modulus may be obtained by using the following conversion equation:

$$\frac{\text{Corrected Young's Modulus}}{0.187} \times \text{Gauge Length (Diameter of Applicator Barrel)}$$

10. Thus, Table B, as corrected, should read as follows:

TABLE B: Instron Compression Testing

Tampon applicator barrels having an outside diameter about 0.67 inches +/- .07 inches and a wall thickness about .027 inches +/- .003 inches

	LOAD lbs. (std. dev.)	YOUNG'S MODULUS psi (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic Applicators	2.22 to 3.59 (0.16)	191.9 to 277.5 (20.4)	0.28 to 0.46 (0.02)
Preferred Composition Applicator	1.74 (0.10)	104.2 (11.8)	0.22 (0.01)

Tampon applicator barrels having an outside diameter about 0.56 inches +/- .06 inches and a wall thickness about .027 inches +/- .003 inches

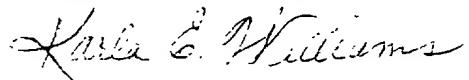
	LOAD lbs. (std. dev.)	YOUNG'S MODULUS psi (std. dev.)	ENERGY lbs.-inch (std. dev.)
Known Branded Thermoplastic Applicators	3.11 to 4.85 (0.28)	239.4 to 474.8 (26.6)	0.40 to 0.62 (0.04)
Preferred Composition Applicator	1.96 (0.20)	113.0 (17.6)	0.25 (0.03)

11. This corrected data supports the present invention. The corrected Young's modulus for the applicator barrel of the present invention having a diameter about 0.56 inches is about 113.0, which is at least one-half of the corrected Young's modulus values obtained for the known branded applicator barrels having approximately the same diameter. The corrected Young's modulus for the applicator barrel of the present invention having a diameter of about 0.67 inches is about 104.2, which is also about one-half of the corrected Young's modulus values obtained for the known-branded applicator barrels having approximately the same diameter. This ratio of corrected Young's modulus for applicator barrels of the present invention to corrected Young's modulus for known branded applicator barrels is consistent with the ratio of the corresponding uncorrected Young's modulus set forth in original Table B of the application.

12. Young's modulus is a constant value for any specific material having a certain size. The composition of the preferred composition applicator barrel is set forth in the application at page 15, Table A, and at page 22, as composition D in Table C. Therefore, any one making such a preferred composition applicator barrel, and then measuring the preferred composition applicator barrel for Young's modulus, would obtain the corrected Young's modulus values as set forth herein.

I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Karla E. Williams

Dated: March 9, 1998